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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,654	10/24/2003	Tomoko Maeda	244295US0CONT	1300

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EXAMINER

AFREMOVA, VERA

ART UNIT PAPER NUMBER

1651

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/691,654	MAEDA ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-41 is/are pending in the application.
- 4a) Of the above claim(s) 26-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/648,899.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/14/04; 10/24/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicants' election with traverse of the Group I, claims 21-25, in the reply filed on 5/13/2005 is acknowledged. The traversal is on the ground(s) that searching all claims not impose a serious burden on the Office. This is not found persuasive because different groups of claims are drawn to products and methods having different scope as claimed and, thus, the references that would be applied to one group of claims would not necessarily anticipate or render obvious the other group(s). Moreover, as to the question of burden of search, classification of subject matter is also an indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists. Clearly different searches and issues are involved with each group. For these reasons, the restriction requirement is deemed proper and is adhered to. The requirement is still deemed proper and is therefore made FINAL.

Claims 26-41 are been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicants timely traversed the restriction (election) requirement in the reply filed on 5/13/2005.

Claims 21-25 are under examination in the instant office action.

Claim Rejections - 35 USC § 112

Claims 21-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 is indefinite with regard to starting, intermediate and/or final cell populations in the claimed method for producing and/or culturing osteoclast precursor cells because the claimed phrase “hematopoietic stem cell-derived cell” means the same as osteoclast precursor cell or preosteoclast cell according to the as-field definitions (page 5, lines 10-11). Thus, it is uncertain what cells are cultured and what cells are produced as claimed.

Claim 21 is rendered indefinite by the phrase “at least 1 to 3 weeks” because it is uncertain where 3 weeks is an upper limit of the culturing period or whether cells are cultured indefinitely beyond the 3-week period (specification page 9, line 16).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Purton et al. (IDS reference; Blood. 1996, Vol. 87, NO. 5, pages 1802-1808).

Claims are directed to a method for producing osteoclast precursor cells wherein the method comprises culturing peripheral blood derived cells in essential medium for mammalian

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cells in the absence of cytokines for 1-3 weeks. Some claims are further drawn to incorporation of serum in the cultured medium and to culture conditions including 35-37 C in 5% carbon dioxide containing air.

Purton et al. disclose a method for producing osteoclast precursor cells wherein the method comprises culturing peripheral blood derived cells in essential medium for mammalian cells MEM supplemented with serum and in the absence of cytokines at 35-37 C in 5% carbon dioxide containing air (page 1802, col. 2, last par. and page 1803, col. 1, line 3) for 14-21 days or for 1-3 weeks (see abstract). The TRAP-positive osteoclast precursor cells have been after 14-21 days of culturing both normal peripheral blood monocytes and mobilized peripheral blood monocytes (page 1806, col. 1, par. 3). Thus, the cited reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purton et al. (U) taken with Matayoshi et al. (IDS reference; Proc. Natl. Acad. Sci. USA. 1996, Vol. 93, pages 10785-10790), US 5,879,940 (Torok-Storb et al.) and Dahl et al. (IDS reference; Annals of the Rheumatic Diseases. 1985, Vol. 44, pages 647-657).

Claims are directed to a method for producing osteoclast precursor cells wherein the method comprises culturing peripheral blood derived cells in essential medium for mammalian

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cells in the absence of cytokines for 1-3 weeks. Some claims are further drawn to incorporation of serum in the cultured medium and to culture conditions including 35-37 C in 5% carbon dioxide containing air. Some claims are further drawn to culturing cells derived from joint fluid as a source of cell of hematopoietic lineage.

The cited reference by Purton et al. is relied upon as explained above for the disclosure of the method for producing osteoclast precursor cells. The osteoclast precursor cells are derived from peripheral blood monocytes as disclosed by Purton et al. The cited reference is missing disclosure related to the use of additional source of osteoclast precursor cells such as joint fluid.

However, US 5,879,940 teaches that stem cells of a hematopoietic lineage can be isolated from various sources including peripheral blood, bone marrow, umbilical cord and other sources (col. 4, lines 54-57). The reference by Matayoshi et al. teaches that osteoclasts are derived from pluripotent precursors of the monocyte macrophage lineage (page 10785, col. 1, par. 1). Further, the reference by Dahl et al. is relied upon for the teaching that synovial tissue or joint fluid derived from patient with rheumatoid arthritis contains substantial amounts of cells of hematopoietic lineage including cells of macrophage nature (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use synovial tissue or joint fluid derived from patient with rheumatoid arthritis as the source of cells of hematopoietic lineage including cells of macrophage nature as taught by Dahl et al. with a reasonable expectation of success in obtaining cells of macrophage nature including osteoclast precursor cells because cells of macrophage nature and/or osteoclast precursors derive from the same pluripotent precursor cells as taught by

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Matayoshi et al. Although the main source of stem cells is a bone marrow, one of skill in the art would have been motivated to use the other sources that might contain fewer precursors cells but are generally easier to obtain than the bone marrow as taught by US 5, 879,940 (col. 6, lines 5-7). The presently claimed starting population such as peripheral blood and joint fluids are generally easier to obtain than bone marrow. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary. The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references.

Therefore, the claims are properly rejected under 35 USC 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

June 6, 2005



VERA AFREMOVA

PRIMARY EXAMINER